NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

JAZZ PHARMACEUTICALS, INC,	:	
	:	**Civil Action No. 10-6108 (ES)**
Plaintiff,	:	
	:	
v.	:	
	:	
ROXANE LABORATORIES, INC.,	:	**OPINION**
	:	
Defendant.	:	

SALAS, DISTRICT JUDGE

Presently before the Court is the parties' request for claim construction. The Court held a *Markman* hearing on April 26, 2012. This Opinion addresses the proper construction of the disputed claim terms.

I. Background

Plaintiff Jazz Pharmaceuticals, Inc. ("Plaintiff" or "Jazz") brings this action against Roxane Laboratories, Inc. ("Defendant" or "Roxane") for patent infringement under 35 U.S.C. § 100, *et seq.* The action arises from Roxane's filing of an Abbreviated New Drug Application ("ANDA") with the United States Food and Drug Administration ("FDA") seeking approval to commercially market a generic version of Jazz's drug XYREM®. Under § 505(a) of the Federal Food Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 355(a), Roxane filed ANDA No. 202-090 ("Roxane's ANDA") seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of 500 mg/ml sodium oxybate oral solution. (Complaint, D.E. 1, "Compl." ¶ 15). Roxane's ANDA filing resulted in this five-count infringement Complaint regarding the patents-in-suit, for which the parties have requested claim construction.

Generally, Jazz alleges, among other things, that Roxane's ANDA constitutes infringement of certain claims of United States Patent Nos. 6,472,431 (the "'431 patent"), 6,780,889 (the "'889 patent"), 7,262,219 (the "'219 patent"), and 7,851,506 (the "'506 patent"), (collectively, the "'431 patent family" or the "'431 family"), and 7,668,730 (the "'730 patent"), 7,765,106 (the "'106 patent"), 7,765,107 (the "'107 patent") and 7,895,059 (the "'059 patent"), (collectively, the "'730 patent family" or "'730 family"), owned by Jazz Pharmaceuticals (collectively, "the patents-in-suit") under 35 U.S.C. § 271(e)(2). The '431 family covers pharmaceutical compositions of sodium oxybate, which is the salt form of gamma-hydroxybutyrate ("GHB"), the active ingredient in Xyrem®. The parties dispute eight claim terms from the '431 patent family.[1] The '730 family covers methods of safely distributing and treating patients with sodium oxybate. Safe distribution of the drug is critical because GHB has been listed as a controlled substance for its illicit uses, including as a "date rape" drug. The parties dispute nineteen claim terms from this family.[2]

Pursuant to Local Patent Rules 4.2(a)-(b), on September 21, 2011, the parties exchanged preliminary claim constructions and identified intrinsic as well as extrinsic evidence in support of their proposed preliminary constructions. On December 2, 2011, the parties submitted their revised joint claim construction and prehearing statement. (D.E. 76, "Joint Claim Construction Br."). On December 5, 2011, the parties filed their opening *Markman* briefs and related declarations and attachments. (D.E. 80, "Jazz Opening Br."; D.E. 77 "Roxane Opening Br.").

[1] By letter dated Apr. 20, 2012, (D.E. 119), the parties agreed that, pursuant to a telephone conference with the Court on April 10, 2012, claim term "wherein . . . is" from the '431 family need not be construed, and that the term should be given its plain and ordinary meaning as understood by a person of ordinary skill in the art. Accordingly, the Court will do so.

[2] In the April 2012 letter, the parties agreed that the following terms from the '730 family need not be construed, and that the terms should be given their plain and ordinary meaning as understood by a person of ordinary skill in the art: "prescription requests"; "prescriptions . . . are processed"; "prescriptions . . . processed for authorization"; "verifying"; "therapeutic"; and "making sure the database available to the DEA . . ." (D.E. 119). Accordingly, the Court will do so.

On February 21, 2012, the parties filed their responsive briefs. (D.E. 100, "Jazz Response Br."; D.E. 98, "Roxane Response Br."). On April 26, 2012, the Court held oral argument for purposes of claim construction.

II. Legal Standard

Claim construction is a matter of law to be determined solely by the court. *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312, 1330 (Fed. Cir. 2005). "It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude." *Id.* (quotations omitted). In construing the terms of a patent, a court should look first to the language of the claim itself. *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996). The terms in the claim "are generally given their ordinary and customary meaning." *Id.* at 1582. "[T]he ordinary and customary meaning of a claim term is the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, *i.e.*, as of the effective filing date of the patent application." *Phillips*, 415 F.3d at 1313. A court "must look at the ordinary meaning in the context of the written description and the prosecution history." *Medrad, Inc. v. MRI Devices Corp.*, 401 F.3d 1313, 1319 (Fed. Cir. 2005). The court should turn to "those sources available to the public that show what a person of skill in the art would have understood disputed claim language to mean." *Innova/Pure Water, Inc. v. Safari Water Filtration Sys., Inc.*, 381 F.3d 1111, 1116 (Fed. Cir. 2004).

To this end, the court should first examine the intrinsic record—the patent itself, including the claims, the specification, and the prosecution history. *Vitronics*, 90 F.3d at 1582 (citing *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995)). The specification "acts as a dictionary when it expressly defines terms used in the claims or when it defines terms by implication." *Id.* Indeed, the Federal Circuit explains that the specification is

"'usually . . . dispositive . . . [and] the single best guide [for] the meaning of a disputed term.'" *Phillips*, 415 F.3d at 1315 (quoting *Vitronics*, 90 F.3d at 1582). It is "entirely appropriate for a court, when conducting claim construction, to rely heavily on the written description for guidance as to the meaning of the claims." *Id.* at 1317. The specification is also an important guide in claim construction because it may contain "an intentional disclaimer, or disavowal, of claim scope by the inventor." *Id.* at 1316.

Additionally, the court should consult the patent's prosecution history because it "provides evidence of how the [Patent and Trademark Office, ("PTO")] and the inventor understood the patent." *Id.* The prosecution history is the complete record of the proceedings before the PTO and includes the prior art cited by the patentee during examination of the patent. *Id.* at 1317. Moreover, the prosecution history "can often inform the meaning of the claim language by demonstrating how the inventor understood the invention and whether the inventor limited the invention in the course of prosecution, making the claim scope narrower than it would otherwise be." *Id.* Indeed, the Federal Circuit has repeatedly emphasized the need to consult the prosecution history to "exclude any interpretation that was disclaimed during prosecution." *Chimie v. PPG Indus.*, 402 F.3d 1371, 1384 (Fed. Cir. 2005) (quotation omitted).

A district court may also examine extrinsic evidence—*i.e.*, "all evidence external to the patent and prosecution history." *Markman*, 52 F.3d at 980; *Phillips*, 415 F.3d at 1317-18 ("[The Federal Circuit] ha[s] authorized district courts to rely on extrinsic evidence . . . ."). Extrinsic evidence consists of testimony by the inventor or by experts, dictionaries, and treatises. *Markman*, 52 F.3d at 980. In particular, a court may find reference to technical dictionaries useful "in determining the meaning of particular terminology . . . ." *Phillips*, 415 F.3d at 1318. However, extrinsic evidence is "less significant than the intrinsic record in determining the

legally operative meaning of disputed claim language." *C.R. Bard, Inc. v. U.S. Surgical Corp.*, 388 F.3d 858, 862 (Fed. Cir. 2004) (quotation omitted).

III. The Disputed Claim Terms

A. The '431 Patent Family

The '431, '889, '219, and '506 patents claim pharmaceutical compositions containing sodium oxybate and methods of making and using the compositions. The parties dispute 8 terms in those patents. The primary location of these terms is claim 1 of the '431 patent.[3] The Court will address each of the disputed terms below.

1. "resistant to microbial growth"[4]

The Court construes this phrase—"resistant to microbial growth"—to mean: "the formulations meet the criteria set by the Food and Drug Administration and the U.S. Pharmacopeia for products made with aqueous bases or vehicles, which for bacteria means not less than a 1.0 log reduction from the initial count at 14 days, and no increase from 14 days count at 28 days, and for yeast and molds, no increase from the initial calculated count at 14 and 28 days."

Jazz proposes the following construction: "the formulations meet the criteria set by the Food and Drug Administration and the U.S. Pharmacopoeia for products made with aqueous bases or vehicles." (Jazz Opening Br. at 5). Roxane proposes: "the formulations meet the

[3] Claim 1 of the '431 patent states:

> A method of rendering an aqueous medium resistant to microbial growth, comprising adding the gamma-hydroxybutyrate salt to the aqueous medium, adjusting the concentration of the gamma-hydroxybutyrate salt in the aqueous medium to a final concentration of at least about 250 mg/ml, and adjusting the pH of the medium to a final pH of about 6 to about 10, so that the medium is chemically stable and resistant to microbial growth.

'431 Patent at 3:22-26.

[4] The term "resistant to microbial growth" appears claim 1 of the '431 patent, claim 1 of the '889 patent, and claims 1 and 4 of the '219 patent.

criteria set by the Food and Drug Administration and the U.S. Pharmacopeia for products made with aqueous bases or vehicles, which for bacteria means not less than a 1.0 log reduction from the initial count at 14 days, and no increase from 14 days count at 28 days, and for yeast and molds, no increase from the initial calculated count at 14 and 28 days, including but not limited to formulations containing greater than about 150 mg/ml GHB to GHB's maximal solubility in an aqueous medium." The '431 patent defines the claim term as follows: "'Resistant to microbial growth' . . . means that the formulations meet the criteria set by the Food and Drug Administration and the U.S. Pharmacopoeia for products made with aqueous bases or vehicles, which for bacteria means not less than a 1.0 log reduction from the initial count at 14 days, and no increase from the 14 days count at 28 days, and for yeast and molds, no increase from the initial calculated count at 14 and 28 days." ('431 Patent at 3:23-32). The Court will define the term as the patent does. *See Phillips*, 415 F.3d at 1315.

Essentially, the parties split the proposed construction into three clauses, agreeing that the first clause should be included in the construction, but disagreeing as to whether the second and third clauses should be included. Jazz argues that the definition should be truncated after "bases and vehicles," because the clauses that follow that language—"which for bacteria . . ." and "which for yeast and molds"—are merely definitions of the U.S. Pharmacopoeia criteria, and not part of the definition of "resistant to microbial growth," and therefore the "which" clauses add nothing to the definition and should be excluded for claim construction purposes. (Jazz's Opening Br. at 5-6). The Court rejects this argument and agrees with Roxane, who argues that the definition should not "stop midsentence and lop off much of applicants' explicit definition . . . ." (Roxane's Opening Br. at 4). The "as used herein" language leading into the definition, ('431 Patent at 32:22-23), indicates that the patentee became his own lexicographer, and

therefore the full definition, including the "which" clauses should be used. Additionally, the "which" clauses should be included because the U.S. Pharmacopoeia's definitions and requirements for microbial resistance change over time, and this language fixes the meaning at the time the patent was sought. Accordingly, the Court construes the definition as containing the "which" clauses.

However, the Court excludes the clause "including but not limited to formulations containing greater than about 150 mg/ml GHB to GHB's maximal solubility in an aqueous medium"—which Roxane proposes should be included in the definition for claim construction purposes. (Roxane Opening Br. at 3). Roxane argues that this clause should be included because claim construction should take into account definitional examples, and without this clause, the definition would lack sufficient specificity. (Roxane's Responsive Br. at 4 (citing *MSM Investments Co. v. Carolwood Corp.*, 259 F.3d 1335, 1339-40 (Fed. Cir. 2001))).

First, Roxane's clause is not found in the definition of the term. Instead, the language merely paraphrases an example from elsewhere in the patent. (*See* '431 Patent at 11:15-26). Second, the language "including but not limited to," followed by an example of one embodiment, ("150 mg/ml . . ."), impermissibly imports an example into the definition. *See Tex. Instruments, Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986). The "but not limited to" language clearly indicates that the example is *non-limiting*. Third, Roxane's supporting decision is distinguishable. Roxane cites *MSM Investments Co., LLC v. Carolwood Corp.*, in which the Federal Circuit found that "the fact that other related patents have claims that are limited to certain pharmacological uses . . . does not compel the conclusion that the claims of the [patent at issue] must be limited to nutritional uses." 259 F.3d at 1340. In *MSM*, examples expanded rather than narrowed the meaning. *See id.* ("[T]he term 'feeding' in claim 1 of the

'878 patent covers *both* nutritional *and* pharmacological uses of MSM® . . . .") (emphasis added). The Court therefore rejects Roxane's proposal to include the third portion of language.

2. "adding the gamma-hydroxybutyrate salt to the aqueous medium"[5]

Within this phrase, the parties primarily dispute the terms "adding" and "aqueous medium." The Court will not construe the terms "adding" or "aqueous medium," because the parties' proposed constructions either do not improve over the "readily apparent" meaning of the terms or the proposals impermissibly import limitations solely for the purpose of improving their infringement and non-infringement positions. *Phillips*, 415 F.3d at 1314 ("In some cases, the ordinary meaning of claim language as understood by a person of skill in the art may be readily apparent even to lay judges, and claim construction in such cases involves little more than the application of the widely accepted meaning of commonly understood words.") (citation omitted). The parties' underlying dispute regarding these terms (and, as the Court will explain below, many others), is whether "adding" means that a pre-made GHB salt is to be taken from *outside* the aqueous solution (*e.g.*, water) and added into it (Roxane's position) or whether "adding GHB" can also mean that the GBH salt forms *in* the water (Jazz's position).

As to "adding," Jazz proposes the construction of "including," which derives from Merriam-Webster's Collegiate Dictionary, 10th ed. (1997) at 13. At the *Markman* hearing, Jazz clarified that it considered "adding" and "including" to be equivalent, and that Jazz's primary position was that the Court should not import the claim limitations that Roxanne proposes (discussed below). (Tr. at 60:7-16 ("Court: Do you think adding [needs] construction?; Jazz: I don't. . . . You can add [the salt], you include it. *Adding means include the member of a group*. We included the salt as a member of the group. [Roxanne] want to say no, [the salt] has to come from . . . a pre-made batch. [Roxane has] all kinds of restrictions that don't appear anywhere in

[5] The term "adding the gamma-hydroxybutyrate salt to the aqueous medium" is in claim 1 of the '431 patent.

the claims.") (emphasis added)). The Court finds that construing "adding" as "including" adds little to the "ordinary meaning of claim language as understood by a person of skill in the art" and that claim construction in this case "involves little more than the application of the widely accepted meaning of commonly understood words." *Phillips*, 415 F.3d at 1314. Accordingly, the Court does not construe "adding" to mean "including."

The Court also rejects Roxane's proposal, construing "adding" to mean "externally adding," limiting the term with the word "externally." Roxane bases its proposal on two separate arguments. First, Roxane argues, "[t]he specification repeatedly describes 'dissolving or mixing' *already existing* NaGHB salt into an aqueous medium." (Roxane's Opening Br. at 5 (citing, *e.g.*, '431 Patent at 3:46-48 ("The amount of GHB that may be mixed or dissolved into an aqueous medium and still be resistant to microbial growth depends upon the pH of the aqueous medium."), *id.* at 4:25-28 ("At the medium to high end of the concentration or content of GHB that may be dissolved or mixed in the aqueous medium . . . .") (emphasis added)). The Court rejects this argument because Roxane points to nothing in the intrinsic evidence that requires the salt to be pre-formed and added from an external location. The fact that the patent describes the salt being "mixed or dissolved" does not mean the salt has to come from outside the aqueous solution. Additionally, the patent's use of the word "in" within the phrase "may be dissolved or mixed *in* the aqueous medium," *id.* at 4:25-28 (emphasis added), demonstrates that the "adding" is not limited in the way Roxane proposes. For example, NaGHB could form *in situ* in the aqueous solution and dissolve from there. Nothing in the patent requires Roxane's limitation.

Second, Roxane supports its position with the prosecution history, arguing "Applicants inserted the 'adding' limitation to overcome a patentability rejection." (Roxane's Opening Br. at 5-6 (citing Ex. I, '431 Patent History, 4/6/02 Notice of Allowability at 2, ROXGBH02926

("Claims 70-78 are allowed over the prior reference[s] . . . [which] fail[] to teach the use of gamma-hydroxybutyrate salt, at the claimed concentration (at last [sic] 250 mg/ml), as an agent that renders 'an aqueous medium' resistant to microbial growth.")); Roxane's Responsive Br. at 7 (citing Ex. Y, '431 Patent History, JPI-00000668-671 (demonstrating that "adding the gamma-hydroxybutyrate salt to the aqueous medium" was added to the claim to satisfy the Examiner)); Tr. at 65:17-21). Therefore, according to Roxane, Jazz's omission of the "adding" step in its proposal violates the claim construction principle that claim terms should not be read out of a patent in the context of a method claim. (Roxane Opening Br. at 6 (citing *Gen. Am. Transp. Corp. v. Cryo-Trans, Inc.*, 93 F.3d 776, 770 (Fed. Cir. 1996))).

The Court rejects Roxane's prosecution history argument. The examiner found the claims distinguished the prior art because the claims "render[ed] 'an aqueous medium' resistant to microbial growth" with particular concentrations of GHB; not, as Roxanne contends, that those concentrations were generated by pre-forming the salt outside the aqueous medium and then putting it inside the medium to achieve resistance. (*See* Ex. I, '431 Patent History, 4/6/02 Notice of Allowability at 2, ROXGBH02926). Roxane makes a leap from the patent history (which demonstrates that the language "adding the gamma-hydroxybutyrate salt to the aqueous medium" was added to satisfy the Examiner) to the inference that "adding" must mean "externally" adding a pre-formed GHB salt. Aside from this inferential leap, Roxane points to no evidence that "adding" was included for a reason related to patentability.

As to construing "aqueous medium," Jazz proposes "more than 50% water," while Roxane proposes, "*pre-existing* aqueous medium." The Court rejects both proposals.

The patent's specification contains the following discussion of "aqueous medium": "As used herein in certain embodiments, an 'aqueous medium' may mean a liquid comprising more

than about 50% water. In certain preferred embodiments, an 'aqueous medium' may be a solution suspension, gel or emulsion of GHB . . . ." ('431 Patent at 3:31-36). Accordingly, Jazz's proposal attempts to turn what an aqueous medium "may" be into what it must be, which would exclude other examples in the specification—such as gels or emulsions—that do not necessarily contain more than 50% water. The Court declines to import a limitation that would exclude examples of aqueous media that "may" be preferred embodiments, and the Court finds that Jazz's context-specific citations to the specification do not support its proposed construction. (*Id.* at 3:37-48 ("Compositions that are resistant to microbial growth are created by dissolving or mixing GHB in an aqueous medium to a concentration or content of greater than of [sic] about 150 mg/ml GHB to the maximal solubility of GHB."), 4:10-13 (same), 4:10-28 (listing various mg/ml amounts)).

The Court also rejects Roxane's proposals to construe "aqueous medium" as "pre-existing aqueous medium" for the same reasons that the Court rejected Roxane's request to add the words "externally" and "pre-made" to the construction: because, as outlined more fully above, nothing in the intrinsic evidence supports a construction of "adding the gamma-hydroxybutyrate salt to the aqueous medium" to be limited to situations where GHB is taken from *outside* an aqueous mixture and placed *into* it. The Court agrees with Jazz's representation at oral argument: "[W]e don't care how [the salt] gets there. Just get there. There is no limitation how it gets there." (Tr. at 59:5-7).

3. "salt"[6]

[6] The term "salt" appears in claims 1 and 2 of the '431 patent. Its use in claim 1 is as follows:

> In certain embodiments, the composition may contain one or more salts. A "**salt**" is understood herein to mean certain embodiments to mean [sic] a compound formed by the interaction of an acid and a base, the hydrogen atoms of the acid being replaced by the positive ion of the base. Various salts, including salts of GHB, are also encompassed by the invention, particularly as pH adjusting or buffering agents. Pharmaceutically acceptable salts, include inorganic acids such as,

The Court construes the claim term "salt" as Roxane proposes, to mean: "a compound formed by the interaction of an acid and a base, the hydrogen atoms of the acid being replaced by the positive ion of the base."[7] (Roxane Opening Br. at 4). The specification provides: "A 'salt' is understood herein to mean certain embodiments to mean [sic] a compound formed by the interaction of an acid and a base, the hydrogen atoms of the acid being replaced by the positive ion of the base." ('431 Patent at 7:1-5). Despite the words "certain embodiments," the parties do not dispute that the patent itself defines salt, and that the Court's construction should therefore include the specification's first clause, "a compound formed by the interaction of an acid and a base." (*See* Tr. at 70:16-20, 73:7-8; Roxane Opening Br. at 4; Jazz Opening Br at 9). However, the parties do dispute whether the second clause, "the hydrogen atoms of the acid being replaced by the positive ion of the base," is merely an example that should not be included in the "definition" (Jazz's position) or part of the "definition" itself (Roxane's position).

Jazz argues that including the second clause into the construction would inappropriately read a limiting example into the claim, violating *Philips*, 415 F.3d at 1323. (Jazz's Opening Br. at 9-10). Jazz argues that reading this limiting example into the claim term's definition would exclude other examples of "salts" mentioned elsewhere in the specification. Salt is not limited to any of the preferred embodiments listed in lines 1-30 of column 7, defining salt. (Jazz's

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> for example, hydrochloric or phosphoric acids, or such organic acids as malic, acetic, oxalic, tartaric, mandelic, and the like. Salts formed can also be derived from inorganic bases such as, for example, sodium, potassium, silicates, ammonium, calcium, or ferric hydroxides, and such organic bases as isopropylamine, trimethylamine, histidine, procaine and the like. Alkali metal salts, such as lithium, potassium, sodium, and the like may be used, preferably with an acid to form a pH adjusting agent. Other salts may comprise ammonium, calcium, magnesium and the like.

'431 Patent at 7:1-30.

[7] The Court has trouble accepting Jazz's argument—that the Court should reject Roxane's proposal because it reads examples out of the definition despite their presence elsewhere in the specification—because, for other terms, Jazz has argued that the patent need not cover every example in the specification. (*Compare* Tr. at 71:24-72:5 (Jazz's argument that the Court should not adopt language that would read examples out of the definition), *with* Jazz's Opening Br. at 7-8 (citing 3:31-33 (Jazz's argument that the Court should adopt language that would read examples out of the definition)).

Responsive Br. at 4 (citing *Tex. Instruments*, 805 F.2d at 1563)). In opposition, Roxane argues that the claim construction should include the first *and* second portions of the definition in the specification because "artificially truncating" the definition at the comma is inappropriate because the portion of language after the comma ("the hydrogen atoms . . .") is not merely an example, it is part of the actual definition. (Roxane's Opening Br. at 4, 6). Roxane also argues that truncating the construction as Jazz proposes would create anomalous scientific results, because one common interaction of an acid and a base is adding HCl (acid) to NaOH (base) to yield NaCL (table salt) and H20 (water). Roxane argues that water would fall into Jazz's construction, but obviously H20 is not a salt. (Roxane's Opening Br. at 4). Jazz counters that, "no one of skill in the art would be misled into thinking that water is a 'salt' based on Jazz's construction." (Jazz's Responsive Br. at 4-5).

The Court finds that including the second clause in the construction is more faithful to the portion of the specification that the parties agree is a definition. First, if this portion of the specification is a definition, it *includes* the second clause. Second, the word "herein" is used once at the beginning of the full sentence and therefore applies to the first and second clauses equally. Third, the sentence immediately *following* the two-clause definition for salt indicates the beginning of the specification's discussion of examples. ('431 Patent at 7:5-28 ("Various salts, including salts of GHB . . . . Pharmaceutically acceptable salts, include inorganic acids such as, for example, hydrochloric or phosphoric acids . . . ."). The existence of the "Various salts" sentence *following* the two-clause definition sentence further reinforces the fact that the language in the two-clause sentence contains a unit of text defining the term, not merely a definition (clause one) with an example tacked on (clause two).

4. "about"[8]

The Court finds that no construction of this claim term is necessary. Jazz proposes a definition of "reasonably close to" and Roxane proposes "20% of the number modified in the appropriate direction(s)." The patent states: "As used herein, the term 'about' generally means within about 10-20%." ('431 Patent at 4:8-9).

Roxane argues that the applicants acted as their own lexicographers, so the plain meaning of "about" is not appropriate in this case, and the term "about" must be construed in the context of the intrinsic evidence. Essentially, Roxane argues that the patent's "general[]" definition is *the* definition. Jazz argues that the patent's use of the word "generally" in its definition of "about" means the suggested percentages are purposefully imprecise, and that Jazz's construction—"reasonably close to"—reflects this general approach, and is supported by the extrinsic dictionary definition of the word. (Jazz's Opening Br. at 11; Jazz's Responsive Br. at 7 (citing *Merck & Co. v. Teva Pharms. USA, Inc.*, 395 F.3d 1364, 1369 (Fed. Cir. 2005) (construing "about" to mean "approximately" without including some specific numeric range))).

The Court rejects both proposals. The Federal Circuit has held that the term "about" does not have a universal meaning in patents and that it depends on the context of the content. *Pall Corp. v. Micron Separations, Inc.*, 66 F.3d 1211, 1217 (Fed. Cir. 1995) ("[T]he use of the word 'about,' avoids a strict numerical boundary to the specified parameter. Its range must be interpreted in its technologic and stylistic context."); *Astrazeneca Pharm. LP v. Handa Pharm., LLC*, No. 08-3773, 2010 WL 4941431, at *4-5 (D.N.J. Nov. 30, 2010) (rejecting proposed definitions for "about" that "limit[ed] the ranges to exact numbers" where nothing in the claim language compelled such an interpretation, and accepting the construction of "approximately").

[8] The term "about" appears in claims 1, 3, and 5 of the '431 patent, claim 1 of the '889 patent, claims 1, 2, and 4 of the '219 patent, and claim 1 of the '506 patent.

In the context of the '431 patent family, "about" modifies pH values and salt concentrations. (*See* '431 Patent Claim 1 at 70:5-12 ("A method of rendering an aqueous medium resistant to microbial growth, comprising adding the gamma-hydroxybutyrate salt to the aqueous medium, adjusting the concentration of the gamma-hydroxybutyrate salt in the aqueous medium to a final concentration of a least about 250 mg/ml, and adjusting the pH of the medium to a final pH of about 6 to about 10, so that the medium is chemically stable and resistant to microbial growth.")). Throughout the specification, the patent repeatedly demonstrates an upper pH limit of 10.3. (*See* '431 Patent at 3:57-58 ("In a preferred embodiment, the pH of said aqueous medium is about 6 to about 7.5. The pH may be from about 3.0 to about 10.3 . . . ."), 4:30-36 ("[T]he pH may be of about 3.9 to about 10.3."), 20:5-9 ("The inventors contemplate that a concentration of greater than about 150 mg/ml of GHB, up to the maximal solubility in aqueous solutions of GHB will be suitably resistant to microbial challenge from about pH 3 to pH 10.3.")). Applying Roxane's proposed definition—importing a 20% limitation, and leaving out the 10% language in the general definition—would consistently lead to pH values in column 3 of the '431 patent well above the apparent upper limit of pH 10.3, and as Jazz argued at the *Markman* hearing, the salt concentration numbers in column 4 of the '431 Patent "would be all over each other and it makes no sense." (Tr. at 78:19-22). The Court agrees that Roxane's proposal does not fit into either context.

Additionally, Roxane's argument that its proposal is supported by an explicit definition in the specification is undercut for two reasons. First, the portion of language to which Roxane points comes after the word "generally," which indicates that the following "definition" is not precise. Second, Roxane's proposal is not faithful to the language following "generally" because Roxane omits the 10% figure from its proposal. Arguing that 20% subsumes 10%, (Tr. at

79:22), is unpersuasive, because if Roxane purports to remain faithful to a particular definition, it should remain faithful to the full definition.

The Court also rejects Jazz's proposal because "reasonably close to" is merely the dictionary definition of a word that would be easy for a person of ordinary skill in the art to understand in the context of the '431 family of patents. Jazz's definition relying on extrinsic evidence, adds no additional understanding. For example, in the context of pH, the patent states that "[t]he pH may be from about 3.0 to about 10.3, namely of about 3.0, about 3.1, about 3.2, about 3.3, about 3.4 . . . or about 10.3," listing every tenth. ('431 Patent at 3:55-4:4; *see also id.* at 4:10-24 (listing concentrations for every ten ml/mg, *e.g.*, "about 230 mg/ml, about 240 mg/ml . . . .")). Because of the patent's extensive list of each one-tenth of a pH value, the definitions for "about 3.1," "about 3.2," and "about 3.3," are clear.

5. "does not contain a preservative"; "free of preservatives"[9]

Within this phrase, the parties dispute the term, "preservative." Jazz proposes, "conventional exogenous substances that are added in addition to the gamma-hydroxybutyrate salt to inhibit chemical change or microbial action," and Roxane proposes, "any substance added to inhibit chemical change or microbial action." The patent provides: "A 'preservative' is understood herein to mean certain embodiments which are substances added to inhibit chemical change or microbial action. Such preservatives may include, but are not limited to, xylitol, sodium benzoate . . . ." ('431 Patent at 7:42-46). The Court construes the term "preservative(s)" to mean: "a substance or substances added in addition to the gamma-hydroxybutyrate salt to inhibit chemical change or microbial action."

[9] The term "does not contain a preservative" appears in claim 4 of the '431 patent, which states, "[t]he method of claim 1, 2, or 3 wherein the medium does not contain a preservative." (70:18-19). The term "free of preservatives" appears in claim 1 of the '889 patent and claims 1 and 4 of the '219 patent. The parties have agreed that the construction of the term "does not contain a preservative" will also apply to the term "free of preservatives." (*See* Ex. A to the Revised Joint Claim Construction and Prehearing Statement, D.E. 76 at 2).

The parties agree that the construction should include the following portion from the specification: "substance[] added to inhibit chemical change or microbial action." The real dispute is what, if anything, to add to that language. Jazz proposes the inclusion of the words "conventional exogenous" to modify "substances" and the phrase "in addition to the [GHB] salt." Roxane proposes the inclusion of the word "any" to modify "substances."

The Court accepts Jazz's proposal to include "in addition to the gamma-hydroxybutyrate salt," because self-preserving GHB formulations are themselves preferred embodiments within the specification, (*see* '431 Patent at 18:1-6, 19:36-20:10), and preferred embodiments should not be excluded from a term's construction. *See Chimie v. PPG Indus.*, 402 F.3d 1371, 1377 (Fed. Cir. 2005) ("[A] construction that would not read on the preferred embodiment . . . would rarely if ever [be] correct . . . ."). Additionally, at the *Markman* hearing, Roxane conceded, "I would be happy to say not including GHB. I mean GHB can be in there." (Tr. at 90:22-23; 97:6-12).

Similarly, the Court rejects Roxane's proposal to include the word "any" to modify "substances," because "any" would include GHB as a "preservative," and therefore the phrase at issue—"free of preservatives"—would *exclude* GHB, a preferred embodiment. The Court agrees with Jazz's argument during the *Markman* hearing that, if you included "any" into the definition, "you have to have a GHB formulation free of GHB. That makes no sense. Cannot be." (Tr. at 86:10-12). Including the word "any" in the construction would inject confusion on an issue on which the parties agree.

The Court also rejects Jazz's proposal to modify the term "substances" with "conventional exogenous." In support of this addition, Jazz argues that the patent prosecution history demonstrates the applicant's clear disavowal of using conventional exogenous substances

for stabilization. Although the Court agrees that the prosecution history does provide support for the proposition that the preferred embodiments do not contemplate the use of conventional exogenous substances for stabilization, the Court finds that the prosecution history statements on which Jazz relies do not rise to the "exacting" level of being a clear disavowal of claim scope, warranting the inclusion of the "conventional exogenous" limitation into the construction. *Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362, 1366 (Fed. Cir. 2012) ("The patentee may demonstrate intent to deviate from the ordinary and accustomed meaning of a claim term by including in the specification expressions of manifest exclusion or restriction, representing a clear disavowal of claim scope.") (citing *Teleflex, Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002)). Some of Jazz's references demonstrate that self-stabilization—instead of conventional preservatives—distinguished the prior art. (*See*, *e.g.*, Ex. 10, August 10, 2001 response to an Office Action, at JPI-00000627 ("None of the [prior art] references, including the admitted prior art, teaches or suggests any method of making a solution of GHB salt resistant to microbial growth other than by adding conventional preservatives.")). Other references demonstrate that conventional exogenous preservatives, (*e.g.*, xylitol), are not used in the patent's preferred embodiments. (*See* Ex. 10 at 627-28 ("[The prior art references] provide no suggestion or motivation that this could be done by adjusting the final concentration of GHB salt to at least about 250 mg/ml and adjusting the pH to the range of about 6 to 10, as recited in claims 66-69. Instead, one would simply add the preservatives disclosed by the references or otherwise conventional in the art, and hope for the best."); Ex. 12, April 1, 2002 Amendment and Response to an Office Action, at JP-00000663 ("[I]t is clearly set forth throughout the present specification that the preferred embodiment is a solution of GHB salt that is resistant to microbial growth without the need to add exogenous preservatives.")).

Accordingly, the Court adopts the patent's definition, adding only "in addition to the gamma-hydroxybutyrate salt" to avoid reading preferred embodiments out of the definition.

6. "pH-adjusting agent"[10]

Jazz proposes that no construction is necessary. Roxanne proposes, "an agent, which is an acid or base, directly added primarily to alter the pH." The Court rejects both proposals and construes the term to be, "compositions that achieve a desired pH," which is consistent with the specification language.

The Court rejects Jazz's proposal not to construe the term because in the context of this patent family, "pH-adjusting agent" is not the sort of non-technical phrase whose meaning is obvious. Additionally, the parties' proposals represent a true conflict, because Roxane's proposal to include "directly added primarily," echoes its other proposed constructions seeking to limit the patent's scope so "that the listed pH-adjusting agents are agents that are added to aqueous media *without any additional step* (*i.e.*, directly) for the principal purpose (*i.e.*, primarily) of adjusting the pH of the aqueous media." (Roxane's Responsive Br. at 14) (emphasis added). Jazz rejects the inclusion of such a limitation.

The Court rejects Roxane's proposal to include "directly added primarily," finding that the portions of the specification cited by Roxane do not support its position. (*See* '431 Patent at 6:36-39 ("In certain other embodiments of the present invention, the pharmaceutical composition may comprise a pH adjusting or buffering agent. Such agents may be acids, bases, or combinations thereof."), 8:54-59 ("comprising admixing GHB and a pH-adjusting or buffering agent in an aqueous medium. In certain embodiments, the method of preparing the

[10] The term "pH-adjusting agent" appears in claim 6 of the '431 patent: "The method of claim 1, wherein said pH-adjusting agent is an organic acid." ('431 Patent at 70:23-24). The term also appears in claim 1 of the '889 patent and claims 1, 3, and 4 of the '219 patent.

pharmaceutical composition further comprises admixing a preservative with the pharmaceutical composition."), 12:50-63 ("[A] pH-adjusting agent may be added to the composition. . . . Compositions of GHB, pH adjusted with malic acid are resistant to both microbial growth and chemical degradation of GHB, and are preferred.")). Similarly, the Court rejects Roxane's prosecution history disclaimer argument because nothing in the prosecution history supports a disclaimer of claim scope warranting the inclusion of "directly added primarily." (*See* Ex. J, '889 Patent History, March 18, 2004 Notice of Allowability at 2, ROXGHB002942).

Because the Court does find that the term should be construed, the Court looks to the specification, which provides: "In certain other embodiments of the present invention, the pharmaceutical composition may compromise a pH adjusting or buffering agent. Such agents may be acids, bases, or combinations thereof." ('431 Patent at 6:36-39). Additionally, the specification provides: "In certain embodiments, the acid may be an organic acid," (6:39-40); "In a preferred embodiment, the acid is malic or hydrochloric acid," (6:52-53); "In certain other embodiments, the pH adjusting agent may be a base," (6:53-54); "In certain other embodiments, the pH adjusting agent may be a mixture of more than one acid and/or more than one base. In other preferred embodiments, a weak acid and its conjugate base are used to form a buffering agent to help stabilize the composition's pH," (6:63-67); "In one embodiment, a salt of GHB comprising an alkali metal may be combined with an acid to create a composition that achieves the desired pH when admixed with an aqueous medium . . . ." (7:18-24). The Court's construction, "compositions that achieve a desired pH," includes all of the examples explicitly listed in the specification, in addition to compositions with a pH of 7.0 that have not been disclaimed. Accordingly, the Court's construction does not read limitations from particular examples into the construction.

The Court rejects Roxane's proposal to include the limitation, "acid or base," because the specification's use of the words "may," "certain embodiments," and "preferred embodiment" demonstrate that the lists of acids and bases are a non-exhaustive group of examples of compositions that act as pH-adjusting agents. (*See* Tr. at 107:22-25). Additionally, nothing in the prosecution history demonstrates a clear disavowal of claim scope, and including "acid or base" in the construction would preclude the use of a composition with a pH of exactly 7.0. (*See* Tr. at 107:9-14). Without a clear disavowal, Jazz is entitled to the full scope of the term, which the Court finds is reflected in the word "composition," which itself appears in the specification, and non-exclusively encapsulates acids, bases, and combinations thereof. ('431 Patent at 7:19-24); *see Elbex Video, Ltd. v. Sensormatic Elecs. Corp.*, 508 F.3d 1366, 1371 (Fed. Cir. 2007) ("Claim terms are entitled to a heavy presumption that they carry their ordinary and customary meaning to those skilled in the art in light of the claim term's usage in the patent specification.") (quotations omitted).[11]

The Court's construction reflects the plain meaning of the term in the context of the '431 patent family.

7. "organic acid"[12]

Jazz proposes, "a substance containing one or more carbon atoms that is capable of yielding a proton (hydrogen ion) in aqueous solution, turning blue litmus paper red in aqueous solutions, ionizing in solution to yield the positive ion of the solvent, reacting with bases to form salts, or accepting electrons in an acid-base reaction," and Roxane proposes "an acid containing

[11] Finally, the Court rejects Roxane's argument under 35 U.S.C. § 112 ¶ 4—that limiting a dependent claim limits the independent claim—because the phrase "pH-adjusting agent" does not appear in claim 1 of the '431 Patent.

[12] The term "organic acid" appears in claim 6 of the '431 patent.

at least one carbon atom that directly acidifies a solution." The Court construes the term to mean, "a substance containing at least one carbon atom that lowers pH."

The parties agree on the definition of "organic," (Tr. at 111:2), and during the *Markman* hearing, the parties agreed on a construction that includes, "a substance containing at least one carbon atom that lowers pH," (Tr. at 114:3-7), so the only question left for the Court is whether to include the word "directly," as Roxane proposes. Roxane summarized the significance of the proposal at the hearing: "What [acids] do is what they directly do, not that they convert three times in a reaction and then finally lower the pH. They do it immediately. That is what I mean by directly. There is no intermediate reaction . . . ." (114:21-25).

The Court rejects Roxane's proposal. The word "directly" does not appear to be in the passages cited by Roxane. (*See* '431 Patent at 20:27-32 ("The feasibility of preparing formulations containing 150 mg/mL of GHB at pH 3, 5 and 7 was established. Solutions containing 150 mg/mL GHB were prepared. The initial pH was greater than pH 7.5 and the final pH was adjusted to 3, 5 or 7 with hydrochloric acid."), 32:58-60 ("Acidulent was added to water and cooled to room temperature. The sodium oxybate was dissolved in the diluted acidulent solution.")). These passages demonstrate methods in which sodium oxybate is added to acidic solutions, without providing clear support for the limitation "directly." Without clear support in the specification or disavowal of the claim's scope in the prosecution history, the Court finds that it would be inappropriate to import the limitation "directly."

8. "dose"[13]

Jazz proposes that no construction is necessary, and Roxanne proposes, "a therapeutic amount of a pharmaceutical composition comprising chemically stable gamma-hydroxybutyrate

[13] The term "dose" appears in claim 1 of the '506 patent.

in an aqueous medium resistant to microbial growth taken by a patient." The Court accepts Jazz's proposal, does not construe the term, and gives "dose" the ordinary and customary meaning the term would have to a person of ordinary skill in the art.

The patent does not define "dose," and the parties' dispute is as follows. Roxane's proposal is rooted in its desire to construe "dose" to refer to the liquid a patient actually ingests. Jazz's proposal is rooted in its desire to include the concentrated liquid in the bottle a patient receives from the pharmacy and then dilutes in water before ingesting. Because this is the real issue, the key portion of Roxane's proposal is "by a patient."

Although Roxane's construction does find support in the specification, its proposal also imports limitations and redundancies unnecessary to the fact-finder's understanding of what dosage means in the context of this claim. (*See* '506 Patent at 8:60-65 ("The invention also provides a method of treating any *therapeutic* category of disorder responsive to GHB, comprising administering to a patient suspected of having such a condition a therapeutic amount of a pharmaceutical composition comprising chemically stable GHB (*e.g.*, 1-10 gms.) in an aqueous medium resistant to microbial growth. *In certain embodiments*, the method of treating a condition responsive to GHB comprises *a patient taking* a first dosage of from about 0.1 g to about 10g . . . .") (emphases added), 72:20-22: ("comprising orally administering *to a patient* afflicted with the condition an aqueous composition comprising a first dose of about . . . ."). The language "certain embodiments" demonstrates that Roxane seeks to read the limitation found in some examples into the construction itself. Additionally, claim 1 of the '506 Patent itself specifies the amount of GHB to be administered, ("comprising a first dose of about 4.5 to about 10 grams of [NaGHB] . . . comprising a second dose of about 4.5 to about 10 grams within

2 to 5 hours . . . "), and therefore construing "dose" would become an "obligatory exercise in redundancy." *U.S. Surgical Corp. v. Ethicon, Inc.*, 103 F.3d 1554, 1568 (Fed. Cir. 1997).

B. '730 Patent Family

The '730, '106, '107, and '059 patents claim methods of using drugs such as sodium oxybate under a restricted distribution system based on the drug's Schedule I status. Jazz argues that no construction is necessary for many of the disputed terms in this patent family, and Roxane argues that construction is necessary based on Jazz's clear disclaimers and disavowals in the patent history, and based on limitations derived from inferences from examples in the specification. Because the patent prosecution history forms the basis of Roxane's core arguments for its proposed constructions of the claim terms in the '730 family, the Court summarizes it here.

First, on October 18, 2006 (Final Office Action) and on Feb. 5, 2007 (Advisory Action), the Examiner rejected the patents in the '730 family as obvious. Second, applicants appealed the rejection, but the Board of Patent Appeals ("the Board") affirmed the rejection on August 31, 2009. (Ex. L '730 Patent History ROXGHB004771). Third, on Nov. 2, 2009, applicants amended the claims and made further representations to the Examiner, distinguishing the prior art. It is on these representations that Roxane bases most of its claim construction arguments with respect to the '730 patent family. With this patent prosecution history in mind, Roxane's three main disclaimer arguments for its claim construction positions in the '730 patent family are as follows:

(1) ***Single*** **or** ***Exclusive*** **Pharmacy and Central Database:** To obtain their patents and to avoid obviousness over the prior art, Roxane argues that the applicants represented that the prior art did not require a "single" pharmacy with a "single" central database for distribution of

all of the prescription drugs, whereas the '730 patent would require a single pharmacy and a single central database. (Roxane's Opening Br. at 11-12). In support, Roxane cites the following patent history:

- Ex. L '730 Patent History
    - July 31, 2006 Interview Agenda at 6, ROXGHB004563: The applicants' agenda with the USPTO included the following "additional limitation" for discussion: "*only way to distribute sensitive drug is through use of the central database*." (emphasis added) The applicants explained that the prior art references, Maradi and Lilly, "alone or combined, suggest that a sensitive drug can only be distributed under control of a single source, or required to be tracked through the use of a single central database. [The '730 patent] provides the ability to track potential abuse patterns with much greater accuracy, and may have been the basis for allowing the life improving drug XYREM®, to make it onto the market."
    - Jan. 17, 2007 Amdt. at 9-10 ROXGHB 004611-12: In their attempts to oppose the obviousness challenge to '730 over the prior art of Ukens, Moradi, Lilly, and Califano, applicants stated: "[The prior art] advocates *away from the use of a single pharmacy*. . . . Ukens does not describe the use of an exclusive computer database. This combination of four references does not provide or suggest a solution to one of skill in the art allowing distribution of a sensitive drug as claimed." (emphasis added)
    - July 18, 2007 Substitute Appeal Br. at 16-23 ROXGHB004689-96: Applicants' appeal brief distinguishes relevant prior art over an obviousness challenge by arguing that the prior art fails "to teach or suggest an exclusive computer database," (4689), "Ukens teaches away from the proposed combination of references," (4692), "independent claim 33 must be read as including a sensitive drug under exclusive control of a central pharmacy. This control is through the exclusive computer database of the central pharmacy. . . . This is different from . . . Moradi which merely provides a pharmacy including a central server without any limitation as to the prescriptions which may be filled." (4695).
    - Dec. 3, 2007 Reply Brief at 2-4, ROXGHB004733-35: Finding fault with the Examiner, applicants argue, "The Examiner gave the claim language 'exclusive computer database' the broadest reasonable interpretation. . . . [T]he broadest reasonable interpretation must be limited by the ordinary meaning of the word at issue. The term 'exclusive' means 'single' or 'sole,' and as pointed out above, [prior art reference] Lilly et al. discloses that each entity typically maintains its own database. That is, there is not an exclusive, single, or sole database disclosed in Lilly et al." (4733).

- Nov. 2, 2009 Amdt. at 9-14 ROXGHB004779-84: In the applicants' amendments to overcome Examiner Najarian's finding of obviousness, they argued, "none of the references, either alone or in combination, discloses 'all prescriptions for [a] sensitive drug are processed only by [an] exclusive central pharmacy using only [an] exclusive computer database' and 'mailing the sensitive drug to the patients only if no potential abuse is found by the patient to whom the sensitive drug is prescribed and the doctor prescribing the sensitive drug . . . ." (4782).

- Ex. M '106 Patent History

  - Mar. 11, 2010 Amdt. at 11-12, ROX GHB005046-47: In response to the Office Action mailed Nov. 17, 2009, denying the application because it was not patentable over Moradi, Ukens, and Melker, applicants filed their Amendment & Response, amending the claims and arguing, "none of the cited references discloses the features of receiving all prescription requests only into an exclusive central computer system or an exclusive computer database, requiring entry of information into the exclusive computer database, and noting, based on the analysis of the potential abuse, misuse, or diversion of the prescription drug and/or the periodic reports, that there is a potential for abuse, misuse or diversion by the patient to whom the prescription drug is prescribed." (5046-47).

- Ex. N '107 Patent History

  - Nov. 3, 2009 Amdt. At 8-12, ROXGHB005271-75: In response to the Office Action mailed on September 14, 2009, in which the Examiner rejected the claims, applicants argued that their proposed amendments distinguished Moradi, Ukens, and Lilly because "these references simply do not relate to the tracking of a particular sensitive drug using an exclusive central pharmacy and an exclusive central database to determine potential abuse by a particular doctor who is permitted to prescribe such sensitive drugs and a particular patient to whom prescriptions are written." (5275).

(2) ***Only*** **the Central Pharmacy:** Second, Roxane uses the patent history to argue that applicants amended the claims to require that all prescriptions be "received *only* at the central pharmacy and that *all* prescriptions [be] processed *only* by the exclusive pharmacy and using *only* the exclusive computer database." (Roxane's Opening Br. at 11-12). In support, Roxane cites the following patent history:

- Ex. L '730 Patent History Nov. 2, 2009 Amdt. at 9 ROXGHB004779: Applicants represented that they "ha[ve] amended the claims so that the prescriptions are received *only* at the central pharmacy and that all prescriptions are processed *only by the exclusive pharmacy and using only the exclusive computer database*." (emphasis added).

- Ex. N. '107 Patent History Nov. 3, 2009 Amdt. at 6 ROXGHB005269: (Same)

(3) Drug Dispensed in a Form Ready for Receipt, not Inventoried for Later: Third, Roxane argues, "[w]hen the exclusive central pharmacy dispenses the drug product, it must be in a form ready for receipt and use by the patient. It would be contrary to the patent's teachings and applicants' representations to the Patent Office to construe the claims to include a situation where the exclusive central pharmacy sends a bulk stock to another pharmacy to keep as inventory for later dispensing to a patient." (Roxane Opening Br. at 12). Roxane's support is as follows:

- Ex. E '730 Patent at 3:34-35: "In a further embodiment, bulk sodium oxybate is manufactured at a single site, as is the finished drug product. Following manufacture of the drug product, it is stored at a facility compliant with FDA Schedule III regulations, where a consignment inventory is maintained."

- Ex. L '730 Patent History Nov. 2, 2009 Amdt. at 10-11, ROXGHB 004780-81: Applicants argued that their amendments distinguished Maradi, which does not require prescriptions for a sensitive drug to be "processed only by the central service station . . . [or] requiring that a drug be distributed only through its disclosed system." (4781). Lilly "does not disclose that all drugs are processed by its system or method using its data storage . . . . [In Lilly] "each user (such as a doctor, hospital, or pharmacy) may maintain its own database . . . ." (4781).

Jazz argues, generally, that "Roxane seeks to wield the prosecution history as a magic wand that it can wave over all of the disputed claim terms to convert their plain and ordinary meanings into Roxane's proposed constructions. Of course, Roxane ignores that '[a]bsent a clear disavowal or contrary definition in the specification or the prosecution history, the patentee is entitled to the full scope of its claim language." (Jazz's Responsive Br. at 14 (citing *Home Diagnostics, Inc. v. LifeScan, Inc.*, 381 F.3d 1352, 1358 (Fed. Cir. 2004))). Jazz argues that the

majority of the disputed terms (*e.g.*, "pharmacy," "only," "at," "all," and "dispensed") have ordinary meanings that do not require construction. (*Id.*).

1. "prescription drug"[14]

Jazz proposes: "an FDA approved finished dosage form that may be dispensed only upon a prescription." Roxane proposes: "a product containing an active pharmaceutical ingredient available by prescription and not based on brand manufacture." The Court's construction is: "an FDA approved dosage form that may be dispensed only upon a prescription."

The intrinsic evidence supports Jazz's proposal to use the words "FDA approved," and "upon a prescription." (Ex. 5 '730 Patent at 1:10-15 ("Sensitive drugs are controlled to minimize risk and ensure that they are not abused, or cause adverse reactions. Such sensitive drugs are *approved* for specific uses *by the Food and Drug Administration*, and *must be prescribed by a licensed physician* in order to be purchased by consumers.") (emphasis added)). However, the Court rejects Jazz's proposal to include the limitation "finished," because its support in the FDA guidelines provides a definition for "drug product" and not "drug" alone. (*See* Ex. 17, 21 C.F.R. § 314 (2002) at JPE-00358852 ("Drug product means a finished dosage form, for example, tablet, capsule, or solution . . . .")). The Court finds no need to import an external definition for a term that does not appear within the claim phrase at issue.

Additionally, the Court rejects Roxane's proposal to add "not based on brand manufacture" into the construction because it is unsupported by the specification, the prosecution history, or the doctrine of claim differentiation, as Roxane argues. "Under the doctrine of claim differentiation, two claims of a patent are presumptively of different scope." *Kraft Foods, Inc. v. Int'l Trading Co.*, 203 F.3d 1362, 1366 (Fed. Cir. 2000).

[14] The term "prescription drug" appears in claims 1, 2, 4, 6, 7, and 11 of the '730 patent, claims 1, 3, 5, and 7 of the '106 patent, claims 1, 2, and 3 of the '107 patent, and claims 1, 3, 5-8, 10, and 14-16 of the '059 patent.

Roxane's citations to the specification do not support its contention that prescription drugs are identified by active ingredient, not the brand manufacturer. (*See* '730 Patent at 1:38-41 ("A drug distribution system and method utilizes a central pharmacy and database to track all prescriptions for a sensitive drug."), 3:14-24 ("A sensitive drug is one which can be abused, or has addiction properties or other properties that render the drug sensitive. One example of such a drug is sodium oxybate, also known as [GHB] . . . which is useful for treatment of cataplexy in patients with narcolepsy. GHB is *marketed under the trademark of Xyrem*® . . . which trademark can be used interchangeably with GHB herein.") (emphasis added)). In fact, the emphasized language referring to "Xyrem®" directly contradicts Roxane's proposal.

Additionally, Roxane's proposal is not supported by the doctrine of claim differentiation. "Under the doctrine of claim differentiation, two claims *of a patent* are presumptively of different scope." *Kraft Foods*, 203 F.3d at 1366 (emphasis added). Roxane argues that the doctrine supports its proposal to include "not based on brand manufacture" in the construction, because, in a later-filed continuation application, Jazz wanted to limit "prescription drug" to a particular brand, and it clearly did so. (Roxane's Responsive Br. at 19 (citing Ex. P, U.S. Pat. Appl. No. 2011/01119085, claim 1 ("*company's* prescription drug"), claim 30 ("prescription drug . . . sold or distributed under a *single trademark*") (emphases added)). The applicant's later intention to limit the claim to a particular brand, Roxane argues, evinces the applicant's intent that the actual language in claim 1 of the '730 Patent at issue for purposes of the instant construction must *not* be limited to brand. (Roxane's Responsive Br. at 19 (citing *Precise Exercise Equip. Inc. v. Chi HsinImpex Inc.*, No. 96-6418, 1998 WL 798163 (C.D. Cal. 1998) (applying the doctrine of claim differentiation to related patents in the same family))). The Court rejects this argument because claims contained in a different patent application are not part of the

intrinsic record and Roxane provides no binding authority to extend the doctrine of claim differentiation in this manner.

2. "selecting . . . multiple controls"; "places controls"[15]

These terms (in addition to the following two terms, "controls selected from the group consisting of" and "the controls comprising") are related to whether the '731 patent family contains an open-ended list of optional controls (Jazz's position) or a mandatory list of controls that must *all* be used (Roxane's position) to prevent the misuse of GHB. As to each term, Jazz proposes that no construction is necessary, and the Court accepts Jazz's proposals.

As to the term "selecting . . . multiple controls"; "places controls," Roxane proposes, "deciding to select more than one control." The Court rejects Roxane's proposal because the term consists of uncomplicated, non-technical language that does not require further construction. Defining "multiple" with "more than one" becomes an unnecessary task in redundancy, and importing the word "deciding" as the definition for "selecting" is circular. Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the

[15] The terms "selecting . . . multiple controls" and "places controls" appear in claims 1, 3, 5, and 7 of the '106 patent, claims 1, 2, 4, and 5 of the '107 patent, and claims 8, 11, and 16 of the '059 patent. Claim 1 of the '107 patent is as follows:

> A computerized method to control abuse of a prescription drug comprising: selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy, the controls comprising communicating prescriptions from a physician to the central pharmacy; identifying the physician's name, license, and DEA (Drug Enforcement Agency) registration information; verifying the prescription; obtaining patient information; verifying the physician is eligible to prescribe the prescription drug by consulting the National Technical Information Services to determine whether the physician has an active DEA number and to check on whether any actions are pending against the physician; providing comprehensive printed materials to the physician; contacting the patient's insurance company if any; verifying patient registry information; providing comprehensive education information to the patient; verifying the patient has reviewed the educational materials; verifying the home address of the patient; shipping via US postal service or a commercial 10 shipping service . . . .

('107 Patent at 8:35-9:25) (emphasis added).

plain meaning of the term as understood by someone of ordinary skill shall apply. The Court discusses its rejection of Roxane's related patent prosecution history arguments below.

3. "controls selected from the group consisting of"[16]

Jazz proposes that no construction is necessary and Roxane proposes, "selected from the group consisting of the listed controls and no others." The Court accepts Jazz's proposal and rejects Roxane's.

Roxane supports its proposal for the inclusion of "and no others," by arguing that the language "consisting of" has special meaning in the patent context, and that that the language requires a closed or Markush group. *See Vehicular Techs. Corp. v. Titan Wheel Int'l, Inc.*, 212 F.3d 1377, 1382 (Fed. Cir. 2000) ("The phrase 'consisting of' is a term of art in patent law signifying restriction and exclusion, while, in contrast, the term 'comprising' indicates an open-ended construction."). In this case, Roxane argues, "consisting of" means "[y]ou can't have other controls. You can have any one of the controls . . . three, four, five, you could have all 23 . . . [but] you couldn't have 24." At oral argument, Jazz conceded that, as a matter of law "consisting of" means a closed group. (Tr. at 154:5-20). The Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning, viewed through the lens of black letter patent law, would be clear to one skilled in the art. The Court attributes to the term its plain meaning as understood by someone of ordinary skill in the art.

4. "the controls comprising"[17]

Jazz proposes that no construction is necessary and Roxane proposes, "including all of the recited controls but open to additional controls." The Court accepts Jazz's proposal and

[16] The term "controls selected from the group consisting of" appears in claims 1, 3, 5, and 7 of the '106 patent and claims 8, 11, and 16 of the '059 patent.

[17] The term "the controls comprising" appears in claims 1 and 4 of the '107 patent.

rejects Roxane's. The key dispute—indeed, the key dispute with all of the terms including the word "controls"—is whether (as Jazz argues) the terms indicate an open-ended list of optional controls, or whether (as Roxane argues) "all" of the controls necessarily must be chosen.

The Court finds that the context provided by the specification clearly demonstrates that not "all" of the controls must be selected, otherwise the word "selecting," (which comes before the term at issue, "the controls comprising") would be read out of the claim. For example, claim 1 of the '107 patent provides: "A computerized method to control abuse of a prescription drug comprising: selecting with the computer processor multiple controls for distribution by said exclusive central pharmacy, the controls comprising communicating prescriptions . . . ." Accordingly, as Jazz argues, and as the Court agrees, in the context of the specification, if "all" of the controls needed to be included, there would be nothing to "select." *See Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 951 (Fed. Cir. 2006) ("[T]he effect of adopting [the party's] proposed claim construction would be to read limitations . . . out of the claim."). Roxane's construction would not permit decision, which would read the contextual terms "selecting" and "multiple" out of the claim. Accordingly, the Court rejects Roxane's proposal. Notably, Roxane's proposal for this claim phrase (requiring the selection of "all" controls) conflicts with its proposal for "controls selected from the group consisting of" for which Roxane proposed to include "selected." The Court construes the terms consistently to include the concept of selection, in accordance with the patent's specification.

Additionally, Roxane's citations to the patent history do not support a clear disavowal. Roxane argues that the patent history demonstrates that the applicant amended the claim from "selected from the group consisting of" to "comprising," thereby clearly disavowing "selected" in favor of a terms that mean "all" controls must be selected. The applicant made this change to

overcome an Examiner's finding that at least two of the controls, but not all of them, were in the prior art. (Ex. N Sept. 14, 2009 Office Action at 6-7, ROXGHB005239-40 ("At the time of the invention, it would have been obvious to a person of ordinary skill in the art to combine the aforementioned features [identifying the patient, the drug prescribed, credentials of the doctor, verifying the prescription, and obtaining patient information] of Lilly and Ukens within Moradi."), Nov. 3, 2009 Amdt. at 2, ROXHB005265 (amending from "selected from the group . . ." to "comprising"))). However, Roxane's patent history argument mistakenly suggests that applicants changed "consisting of" to "comprising" in order to overcome a rejection. Indeed, as Jazz points out, "the applicants submitted more than eight pages of 'Remarks' with their amendments, but they did not mention the amendment from "consisting of" to "comprising" at all, let alone in a way that supports Roxane's assertion that the amendment was made to overcome a rejection. (Jazz's Responsive Br. at 33 (citing Ex. N. at ROXGHB005269-77)).

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

5. "exclusive"[18]

Jazz proposes that no construction is necessary, and Roxane proposes, "sole." The Court's construction is "single or sole," which is consistent with the intrinsic evidence.

The Court construes the term because the patent prosecution history and the parties' representations at oral argument make clear that confusion has surrounded the term. For example, in the applicant's reply brief on appeal, applicants explicitly narrowed the definition of "exclusive" in an effort to distinguish the prior art. Finding fault with the Examiner, applicants

[18] The term "exclusive" appears in claims 1-3 and 7-11 of the '730 patent, claims 1-8 of the '106 patent, claims 1 and 4 of the '107 patent, and claims 1, 2, 6, 7, 9, 10, and 12-15 of the '059 patent.

argued, "[t]he Examiner gave the claim language 'exclusive computer database' the broadest reasonable interpretation. . . . [T]he broadest reasonable interpretation must be limited by the ordinary meaning of the word at issue. *The term 'exclusive' means 'single' or 'sole,'* and as pointed out above, [prior art reference] Lilly et al. discloses that each entity typically maintains its own database. That is, there is not an exclusive, single, or sole database disclose in Lilly et al." (Ex. L Dec. 3, 2007 Reply Br. at 2, ROXGHB004733; Tr. at 174:9-14 ("If you remember, after the examiner rejected all the claims as obvious, [on] the applicant's appeal, and the Board tried to determine what was meant by the term exclusive in the context of the phrase 'exclusive central database.' And . . . the Board, says well, the applicants are telling us it means *single or sole*.") (emphases added)). In contrast to Roxane's other disavowal arguments, the patent prosecution for "exclusive" clearly sets forth the applicant's position.

Accordingly, rather than perpetuating the confusion that has persisted, the Court construes the term as it was clearly set forth in the patent prosecution history, as "single or sole."

6. "pharmacy"[19]

Jazz proposes that no construction is necessary, and Roxane proposes, "a place where drugs are compounded or dispensed from a supply stock." The Court accepts Jazz's proposal.

The Court rejects Roxane's proposal because it is rooted in an unsupportive portion of the specification. Roxane cites the following: "The inventory is owned by a company, and is managed by a central pharmacy, which maintains the consignment inventory. Xyrem® is distributed and dispensed through a primary and exclusive central pharmacy, and is not stocked in retail pharmacy outlets.")). ('730 Patent at 3:38-42). The Court finds that the portion of the specification Roxane cites is not a definition, and even if it were a definition, it does not contain

[19] The term "pharmacy" appears in claims 1-3 and 7-11 of the '730 patent, claims 1, 3, 5, and 7 of the '106 patent, claims 1, 2, 4, and 5 of the '107 patent, and claims 1, 2, and 6-16 of the '059 patent.

"supply stock" or "compounding," words which do not add understanding to the plain and ordinary meaning of "pharmacy." Additionally, because there is no confusion as to the meaning of the term, it is not necessary to address the extrinsic dictionary meaning set forth by Roxane.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

7. "only"[20]

Jazz proposes that no construction is necessary, and Roxane proposes, "and no other." The Court finds that no construction is necessary.

Roxane's proposal is rooted in its desire to limit pharmacy to being one exclusive pharmacy, but the Court finds nothing in the patent prosecution history, (*e.g.*, Ex. L Aug. 31, 2009 Board Decision at 12, ROXGHB4762), or the specification, (*e.g.*, '730 Patent Figs. 2A-2C, 3:62-4:1, 3:35-45), that requires an explicit limitation in the construction. Although certain embodiments describe such a pharmacy, nothing in the patent requires the inclusion of Roxane's proposed language, and the Court declines to read particular embodiments into the construction.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

8. "at"[21]

Jazz proposes no construction is necessary, and Roxane proposes, "located at." At oral argument, the parties agreed that the dispute in numerous terms, including "at" related to the

[20] The term "only" appears in claims 1, 2, and 7-11 of the '730 patent, claims 1, 3, 5, and 7 of the '106 patent, claims 1 and 4 of the '107 patent, and claims 1, 6, 9 and 12-14 of the '059 patent.

[21] The term "at" appears in claims 1, 2, and 7-11 of the '730 patent, claims 1 and 4 of the '107 patent and claims 1, 6, 9, and 12-14 of the '059 patent.

concept of exclusivity. Essentially, the undercurrent of Roxane's argument is that, "[t]here can really be just the one database, the one pharmacy. Any and all, this is the same thing. It really comes back to the same thing." (208:1-3). Jazz argues that the terms do not require such a limitation. The Court agrees.

Roxane argues that it construction conveys that the location of the computer processor that receives all prescription requests is "only at the exclusive pharmacy," ('731 Patent Claim 1), and therefore the computer processor must be located at the pharmacy. The Court finds that adding the word "located" to add meaning to "at" injects redundancy. Additionally, "located at," is not clearly supported by the prosecution history, (Ex. L Nov. 2, 2009 Amdt at 9, ROXGHB004779-84), and accordingly, the Court attributes to "at" its plain and ordinary meaning to one skilled in the art.

9. "associated"[22]

Jazz proposes no construction is necessary, and Roxane proposes, "located either at or remote from, but not both." The Court accepts Jazz's proposal.

In support of its position, Roxane cites embodiments where the external database is "used in place of" the internal database. ('730 Patent Figure 1 & 3:67). However, this portion of the specification makes clear that it is only "one embodiment," which would be inappropriate to read into the construction. Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

10. "all"[23]

[22] The term "associated" appears in claims 1 and 2 of the '730 patent, claims 1, 3, and 7 of the '106 patent, and claim 1 of the '059 patent.

Jazz proposes that no construction is necessary, and Roxane proposes, "every single one, no exceptions." Roxane's construction reflects its position that the applicant included a limitation to distinguish a situation where, before including the words "any and all," "there could be a patient or doctor sending [or] . . . having their own little database, or a pharmacy having it." (Tr. at 208:5-10). Again, Roxane's proposal reflects its view on the concept of exclusivity.

Although the Court's review of Roxane's citations to the patent history does show that the claims were amended to include the word "all," the record does not provide support for Roxane's proposal of "every single one, no exceptions." (*See* Ex. L Dec. 31, 2009 Notice of Allowability at 10-11, ROXGHB004805-06 (demonstrating that the patent claims would be allowed over the prior art because "the closest prior art of record does not teach or fairly suggest that *all* prescriptions for the prescription drug [GHB] are processed *only by the exclusive central pharmacy using only the exclusive computer database*") (emphasis in the original record). The prosecution history ascribes no special meaning to the word "all" over its common understanding. Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

11. "database"[24]

Jazz proposes that no construction is necessary, and Roxane proposes, "database containing all relevant data related to the distribution of the drug and the process of distributing it, including patient, physician and prescription information." The Court accepts Jazz's proposal.

[23] The term "all" appears in claims 1, 2, and 7-11 of the '730 patent, claims 1, 3, and 5-7 of the '106 patent, claims 1 and 4 of the '107 patent, and claims 1, 6, 9, and 12-14 of the '059 patent.

[24] The term "database" appears in claims 1-3 and 7-11 of the '730 patent, claims 1, 3, and 5-7 of the '106 patent, claims 1 and 4 of the '107 patent, and claims 1, 2, 6, 9, and 12-14 of the '059 patent.

Although the patent history does contain the language Roxane proposes, the language defines, "exclusive computer database," and not "database," the Court's focus of construction here. (*See* Ex. L Aug. 31, 2009 Board Decision at 9, ROXGHB004759 ("[A]s used in the claims in light of the Specification as it would be interpreted by one of ordinary skill in the art is that [the claim term '*exclusive* computer database'] is a central computer database exclusive of other databases that 'contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information.'") (emphasis added) (citing '730 Patent at 2:10-12); *see also* Tr. at 213:8-14)). Because the patent history's focus was "exclusive computer database," the citation is off-point, and Roxane's proposal merely reflects its recurring position on exclusivity.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

12. "control"[25] and "maintains"[26]

The parties' dispute as to both of these terms relates to Roxane's contention that, "both of these [terms] talk about whether the pharmacy is the only one that has the right to write on to the database. . . . Requiring entering of the information, into an exclusive computer database under exclusive control of the central pharmacy." (Tr. at 215:25-216:2). Again, therefore, Roxane's contention relates to its exclusivity contention.

As to "control," Jazz proposes that no construction is necessary, and Roxane proposes, "write accessibility." In support of its construction, Roxane cites three columns of examples

[25] The term "control" appears in claims 1, 2, and 7-11 of the '730 patent, claims 1, 6, 9, and 12-14 of the '059 patent.

[26] The term "maintains" appears in claims 1 and 4 of the '107 patent.

from the patent that Roxane synthesizes into its proposal, but nothing in the columns actually defines the term "control." (*See* Roxane's Opening Br. at 20 (citing '730 Patent at 4:7-7:25)). The Court declines to read examples into the construction where construing "control" would not increase the understanding of one skilled in the art.

As to "maintains," Jazz proposes that the term needs no construction, and Roxane proposes, "has write access to." Roxane points to nothing in the specification or the patent prosecution history that supports its construction, and Roxane has not convinced the Court that the term requires construction.[27]

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

13. "confirming . . . patient"[28]

Jazz proposes that no construction is necessary, and Roxane proposes, "contacting the patient and the patient responding." Roxane's position reflects its view that the specification "requires both an action by the pharmacy, and the patient." (Tr. at 220:4-5). Although the specification contains examples that support this concept, ('730 Patent at 1:53-56, 5:27-41, 61-63), the Court declines to read limitations from examples into the construction. Additionally, Jazz pointed out during the *Markman* hearing that logic does not require confirmation by a patient: "If I hand something to you, I don't have to confirm with you that you received it. I

[27] Additionally, Jazz convincingly argues that Roxane's attempts to read embodiments into the claims would support Roxane's proposed distribution system for its ANDA drug, which "employ[s] multiple pharmacies, and not a single exclusive pharmacy, having write access to the central database." (Jazz's Responsive Br. at 23 (citing Ex. 18 at 31199 (Roxane's proposed distribution strategy), Ex. 19 at ROXGBH031204-06, 08 (Roxane's proposed ANDA drug), and Ex. 20 at ROXGHB031314-19, 21, 27, 30, 32) (Roxane's proposed Risk Evaluation and Mitigation Strategy ("REMS")))).

[28] The term "confirming . . . patient" appears in claims 1, 2, and 7-19 of the '730 patent, claims 1, 3, 5, and 7 of the '106 patent, claims 1, 2, 4, and 5 of the '107 patent, and claims 1, 6, 8-14, and 16 of the '059 patent.

know you received it. There is no confirmation necessary. And this system as well. If the pharmacist hands it to you and says, 'here,' you don't need to shake your hand or wave, I got it." (Tr. at 220:17-23). The Court agrees that no such limitation is appropriate based on the intrinsic evidence.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

14. ". . . to . . . patient"[29]

As to ". . . to . . . patient," Jazz proposes that the term needs no construction, and Roxane proposes, "to the patient in a dispensed form." The parties agreed that this term relates to "confirming . . . patient," and that both terms relate to Roxane's argument for exclusivity. (*See* Tr. at 223:12-13). Although Roxane cites to portions of the specification in support of the limitation "in a dispensed form," nothing in those citations contains that limitation, (Tr. at 224:7-8), and the Court declines to import limitations from examples into the construction.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

15. "dispensed"[30]

Jazz proposes that no construction is necessary, and Roxane proposes, "prepared in a form suitable for providing to an individual patient." The Court accepts Jazz's proposal.

[29] The term ". . . to . . . patient" appears in claims 1, 2, and 7-11 of the '730 patent, claims 1 and 4 of the '107 patent, claims 1, 3, 5, and 7 of the '106 patent, and claims 1, 6, 7, 9, 10, and 12-15 of the '059 patent.

[30] The term "dispensed" appears in claims 7, 10, and 15 of the '059 patent.

Roxane's proposal "means [the pharmaceutical] . . . . [c]an't be a stock supply. . . . We are trying to distinguish when the exclusive central pharmacy sends it to the patient, it is in a form suitable for providing to an individual patient." (Tr. at 225:20-226:1). In support of its position, Roxane cites claim context, ('059 Patent claim 7 at 9:53-55 ("The computerized method of claim 6, wherein providing the prescription drug to the patient comprises the central pharmacy authorizing the prescription drug to be dispensed to the patient by another pharmacy.")), and an extrinsic dictionary definition. The Court finds no direct support for the limitations set forth by Roxane, and it finds that the limitation "to an individual patient" injects redundancy. *See U.S. Surgical Corp.*, 103 F.3d at 1568 (holding that claim construction is not an "exercise in redundancy").

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

16. "computer system"[31]

Jazz proposes that the term needs no construction, and Roxane proposes, "a computer system that is located at the exclusive central pharmacy," further linking its proposal to its argument of exclusivity. The Court accepts Jazz's proposal.

Roxane seeks to import the limitation that the computer system (such as the one in the '106 Patent in Figure 1) is located at the exclusive central pharmacy. (*See* '106 Patent Figure 1 & 2:19-37 ("The exclusive central database contains all relevant data related to distribution of the drug and process of distributing it, including patient, physician and prescription information . . . Fig. 1 is a block diagram of a computer system for use in implementing the

[31] The term "computer system" appears in claims 1-5, 7, and 8 of the '106 patent.

system and method of the present invention.")). Roxane uses this example to import the limitation that because all the requests are received at the exclusive central pharmacy, then the exclusive central computer system must be located at the exclusive central pharmacy. The Court finds that no such limitation—whether the computer system can be remote or has to be located at a certain place—flows from the specification, and that, in defining "computer system" with a construction that begins with "computer system . . . ," Roxane admits the self-evident nature of the term.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

17. "shipping"; "shipment"[32]

Jazz proposes that no construction is necessary, and Roxane proposes, "sending of the prescription drug in dispensed form by carrier." The Court accepts Jazz's proposal.

Roxane's points to examples in the specification to support its construction, relying on examples, in which, after preparation, the drugs are shipped via courier or by mail. (*See*, *e.g.*, '730 Patent at 1:61-62 ("courier service's tracking system is used to confirm delivery"), 3:43-45 ("US Mail"), and 5:57-58 ("USPS"))). However, as with related terms, the Court will not read limitations from examples into the construction.

Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

18. "a separate database"[33]

[32] The terms "shipping" and "shipment" appear in claims 1, 3, 5, and 7 of the '106 patent and claims 1, 2, 4 and 5 of the '107 patent.

Jazz proposes that no construction is necessary, and Roxane proposes, "a database other than the exclusive central database." The Court accepts Jazz's proposal.

Roxane argues that the term appears in claim 3 of the '107 Patent, which depends from claim 1. Claim 3 is: "The method of claim 1 which further comprises consulting a separate database to verify that the medical doctor is eligible to prescribe the drug." Claim 1 refers to the exclusive central pharmacy that maintains a central database, and therefore when claim 3 refers to a "separate" database, it must be referring to a database other than the exclusive central database. (Roxane's Opening Br. at 29). The Court finds that the language of the claim term is clear on its face. Accordingly, the Court agrees with Jazz that no construction of this term is necessary and finds that its ordinary and customary meaning would be clear to one skilled in the art. Therefore, the plain meaning of the term as understood by someone of ordinary skill shall apply.

IV. Conclusion

For the reasons set forth above, the disputed terms at issue will be construed as indicated. An appropriate Order shall accompany this Opinion.

/s/ Esther Salas

Dated: September 14, 2012 **Esther Salas, U.S.D.J.**

[33] The term "a separate database" appears in claims 3 and 6 of the '107 patent.